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in patients treated with duloxetine vs. placebo that was significantly ($p < 0.05$) more frequent regardless of concomitant NSAID use. In addition among NSAID users, patients treated with duloxetine vs. placebo reported significantly more hyperhidrosis ($p < 0.05$); and constipation ($p < 0.01$) was reported significantly more frequently among the non-NSAID users.

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COMPARISON OF DIFFERENT EXPERIMENTAL DESIGNS TO EVALUATE THE EFFICACY OF AN INTERVENTION IN OSTEOARTHRITIS PATIENTS

D. Martinez-Puig[1], C. Chetrit[1], I. Möller[2]. *[1]BIOIBERICA S.A., Palafolls, Spain; [2]Inst. Poal de Reumatologia, Barcelona, Spain*

Purpose: The design of a clinical trial to test the efficacy of an intervention in osteoarthritis patients is strongly hampered by different factors such as the absence of a fully validated biomarker, the magnitude of the placebo effect and the enormous variability associated to the clinical outcomes. The objective of this study is to compare the validity and usefulness of different clinical trial designs to test the efficacy and safety of a food supplement for the management of knee osteoarthritis.
Methods: In order to study the effect of the trial design on the results achieved, 2 clinical trials testing the same product for the management of osteoarthritis (Hyal-Joint®, Bioiberica, Spain), have been compared. The first clinical trial (n = 71) used retrospective data from consecutive patients fulfilling inclusion criteria (moderate to severe knee OA coursing with synovitis) who were treated with Hyal-Joint (80 mg/d) or acetaminophen (500 mg/d). The second trial used the same sample size (n = 70) and same inclusion criteria, but the study was prospective and compared the treatment with Hyal-Joint (80 mg/d) or with placebo (80 mg/d) in a double-blind design. Progression of pain intensity (Huskisson's VAS) has been used as one of the clinical outcomes in both trials. Data from a subsequent prospective double-blind placebo-controlled clinical trial (n = 40) using alternative clinical outcomes has also been discussed. In this trial, instead of using traditional clinical outcomes such as pain perception, joint function was evaluated using standard isokinetic assessment (Biodex system 3 for measuring maximal muscle strength, total work and power mean).
Results: Results from the retrospective trial showed a 49.1% pain reduction from basal values after 3 months of treatment with Hyal-Joint, while the reduction associated to the treatment with acetaminophen was only of 23.1%. Differences between treatment groups were statistically significant ($P < 0.05$). Results from the prospective trial showed the same pain reduction from the basal values associated to the treatment with Hyal-Joint during 3 months (47.9%), but the reduction associated to the placebo treatment was of 39.6%, and differences between treatments groups only tended to reach statistical significance ($P > 0.05$). Interestingly, the pain relief associated to the placebo treatment is statistically higher than pain relief associated to acetaminophen ($P < 0.05$). On the subsequent clinical trial, statistically significant improvements were obtained compared to the placebo group even using a lower sample size (n = 40). The increase of the maximum peak torque of the knee extensors at 3 months compared to baseline was 6.5 ± 5.8 Nm for the active group and -1.0 ± 7.1 Nm for the placebo group at 240°/s ($P < 0.05$). The same pattern of response was obtained for total work ($P = 0.0588$) and power mean ($P < 0.05$).
Conclusions: The overall results show that variability of traditional clinical outcomes and the size of the placebo effect could difficult the obtaining of statistical results in osteoarthritis trials. According to the results, one possible strategy to overcome these handicaps could be the use of purely objective data such as the isokinetic assessment of the affected joint.

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LONG-TERM EFFICACY OF SEQUENTIALLY PROGRAMMED MAGNETIC FIELD (SPMF) THERAPY IN PATIENTS WITH OSTEOARTHRITIS OF THE KNEE

V.G. Vasishta. *SBF Hlth.care & Res. Ctr. Pvt.Ltd., Bangalore, India*

Purpose: A study to demonstrate the efficacy of SPMF therapy on 195 patients (390 knees) with clinically and radiologically confirmed osteoarthritis (OA) of the knee, was published in the Scientific Medicine journal in 2009. The results showed an increase in cartilage thickness measured using MRI at three months follow-up compared to pre-treatment values**.** The present follow-up study was conducted, using the Knee Society clinical rating system, to demonstrate the long-term efficacy of SPMF, on varying grades of severity of OA.
Methods: This study was designed to be a prospective non-randomised clinical evaluation of SPMF therapy.
SPMFs are non-thermal and non-ionising electromagnetic fields, working on the principle of altering cell membrane potential by generating piezo-electric stimulus, resulting in cartilage and bone regeneration. When these fields are precisely focused on the tissues, they aid in regeneration of cartilage by the amplification of IGF-1, synthesis of proteoglycan, normalisation of the electromagnetic fileds in and around the Centrioles, and 'up-regulation' of HSR/HSF-1 pathways.
175 patients aged 30 years and above, with Grade III/IV OA (Kellgren & Lawrence grading system) of the knee, who had undergone SPMF therapy 9 months earlier were enrolled after obtaining their written consent.
The 9-month follow-up data were collected along the lines of previously collated pre-treatment and follow-up data. The main outcome measures included differences in pre-treatment parameters compared to the outcomes after SPMF therapy at intervals of 21 days, and 3 months and 9 months after completion of the therapy. Additionally, adverse effects to treatment were also recorded at 9-month follow-up.
Results: Statistical analysis of the collected data demonstrated an improvement in TFS scores from 39.64 (SD = 21.53) pre-treatment to 47.84 (SD = 18.54) at 21 days, 56.92 (SD = 16.47) at 3 months, and 61.20 (SD = 16.63) at 9 months follow-up.
The TKS score was 53.08 (SD = 17.39) at pre-treatment, which improved to 73.44 (SD = 13.61), 78.64 (SD = 12.26), and 83.32 (SD = 11.63) at 21 days, 3 months, and 9 months, respectively.
Participants with grade III OA showed an improvement in TFS from a pre-treatment score of 48.50 (SD = 33.46) to scores of 57.25 (SD = 23.25), 65.13 (SD = 21.02), and 71.62 (SD = 20.13) at 21 days, 3 months, and 9 months, respectively. For grade IV OA, the TFS score of 35.47 (SD = 12.15) pre-treatment, improved to 43.41 (SD = 14.63), 53.06 (SD = 12.80), and 56.29 (SD = 12.55) at 21 days, 3 months, and 9 months follow-up, respectively.
TKS scores for grade III OA improved from 63.63 (SD = 23.08) pre-treatment, to 78.62 (SD = 13.39), 83.87 (SD = 12.83) and 87.50 (SD = 14.28) at 21 days, 3 months, and 9 months follow-up, respectively. Similarly, the TKS scores for grade IV OA increased from 48.12 (SD = 11.78) pre-treatment to 71.00 (SD = 13.39), 76.17 (SD = 11.55), and 81.35 (SD = 10.04) at 21 days, 3 months and 9 months, respectively.
Conclusions: This study proves that SPMF therapy is an effective treatment modality for OA of the knee, as demonstrated through significant improvements in TKS and TFS scores at 21 days, 3 months and these scores are maintained over the follow up period of 9 months. In addition, the study also provides evidence to indicate that SPMF therapy improves outcomes in all grades of OA. This therapy should be a first line of treatment for OA due to its non-invasive nature, long term efficacy and since it can be provided on an out-patient basis.

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THE PRELIMINARY REPORT OF ENHANCED ROLE OF PLATELET-RICH PLASMA (PRP) WITH ARTHROSCOPIC MICROFRACTURE IN EARLY-STAGED OSTEOARTHRITIS OF KNEE

J-D. Kim, G. Lee, G-H. Jung. *Kosin Univ. Gospel Hosp., Busan, Korea, Republic of*

Purpose: Platelet-Rich Plasma (PRP) is a natural concentrate of autologous blood growth factors experimented in different fields of medicine in order to test its potential to enhance tissue regeneration, and so was emerged as a treatment option for tendinopathies and chronic wounds. In addition to release of growth factors, PRP also promotes concentrated anti-inflammatory signals including interleukin-1a, which has been known to be a focus of emerging treatments for osteoarthritis. In cartilage defect of knee, arthroscopic microfracture is the most widely utilized cartilage restoration technique worldwide, and the results for most osteoarthritis patients are good, especially in the short term. However, according to many reports about this technique, the results of arthroscopic microfracture were not good in the patients of larger defects (>4 cm^2), older patients (age >40 years), and these factors likely influence on an overall observation that the results of microfracture tend to deteriorate over time, particularly after 2 years. Our authors suggested that the tissue-regenerative property of PRP can be helpful for enhancing the effect of the microfracture, but no references about this theory were found. The primary objective is to study the application of PRP with